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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------------------------------------------------------------------------------------|-------------|----------------------|---------------------|------------------|
| 09/869,565 | 10/17/2001 | Thomas J. Gardella | 0609.4730000 | 4604 |
| 28393 | 7590 | 06/21/2006 | EXAMINER | |
| STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C. 1100 NEW YORK AVE., N.W. WASHINGTON, DC 20005 | | | HOWARD, ZACHARY C | |
| | | | ART UNIT | PAPER NUMBER |

1646

DATE MAILED: 06/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action
Before the Filing of an Appeal Brief**

Application No.

09/869,565

Applicant(s)

GARDELLA ET AL.

Examiner

Zachary C. Howard

Art Unit

1646

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 18 May 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).


4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: 25,26,29,32-38 and 41.
Claim(s) objected to: _____.
Claim(s) rejected: 24,27,28,30,31,39,40,42 and 43.
Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☐ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____
13. ☒ Other: See Continuation Sheet.


GARY B. NICKOL, PH.D.
PRIMARY EXAMINER

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Continuation of 5. Applicants' reply has overcome the following rejection(s): All rejections of claims 20-23 are moot in view of Applicants' cancellation of these claims. Furthermore, Applicants' reply has overcome the rejection of claims 24 and 27 under 112, 1st paragraph for failing to comply with the enablement requirement and the written description requirement; and has overcome the rejection of claims 24, 27 and 28 under 112, 2nd paragraph as indefinite for failing to particularly point out and distinctly claim the subject matter regarded as the invention.

Continuation of 13. Other: The examiner was previously unable to determine the limitations placed on the polypeptide that is expressed by the cell used in the method of claims 24, 27 and 28; therefore the claims were rejected under 112, 2nd paragraph as indefinite. Applicants' amendments to claims 24, 27 and 28 clarify the limitations placed on said polypeptide and have therefore overcome said rejection. However, as amended the claimed polypeptide is not limited to one that "comprises a deletion of the extracellular amino-terminal ligand binding domain of a PTH-1 receptor" (as in claims 25 and 26). Instead, claims 24, 27 and 28 are directed to a polypeptide encoded by a polynucleotide "having" a nucleotide sequence that has a deletion of the extracellular domain. The term "having" is a transitional phrase that in view of the instant specification is interpreted as "comprising". The full-length sequence with a deletion of the extracellular domain is equivalent to the sequence of the remainder of the protein (i.e., amino acid residues 23-435 of SEQ ID NO: 2 which are encoded by nucleic acid residues 67-1320 of SEQ ID NO: 1). Therefore, the genus of claimed polypeptides encompasses the full-length PTH-1 receptor, because said full-length sequence comprises the remainder of the protein (amino acid residues 23-435). Therefore, claims 24, 27 and 28 encompass method using cells expressing a full-length PTH-1 receptor. As set forth previously, U.S. Patent 5,494,806 teaches methods of screening using the cells expressing the full-length PTH-1 receptor. Therefore, claim 28 remains rejected under 102(b) for the reasons set forth previously, and claims 24, 27, and new dependent claims 30, 31, 39, 40, 42 and 43 are added to this rejection. New dependent claims 29, 38 and 41 are not included in this rejection because they are limited to particular embodiments wherein the cell comprises a polynucleotide having a nucleotide sequence of 1-1320 of SEQ ID NO: 1 or 1-435 of SEQ ID NO: 2; these particular sequences include a fusion of the signal sequence peptide directly to the remainder of the protein (missing the ECD domain) and therefore are not anticipated by the '806 patent.